

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed April 10, 2009. Claims 1-20 were pending and rejected in view of cited art.¹ Claims 7-8, 13-14, and 17-20 are canceled, claim 1 is amended, and new claims 21-27 are added. Claims 1-6, 9-12, 15-16 and 21-27 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

B. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. §102/103

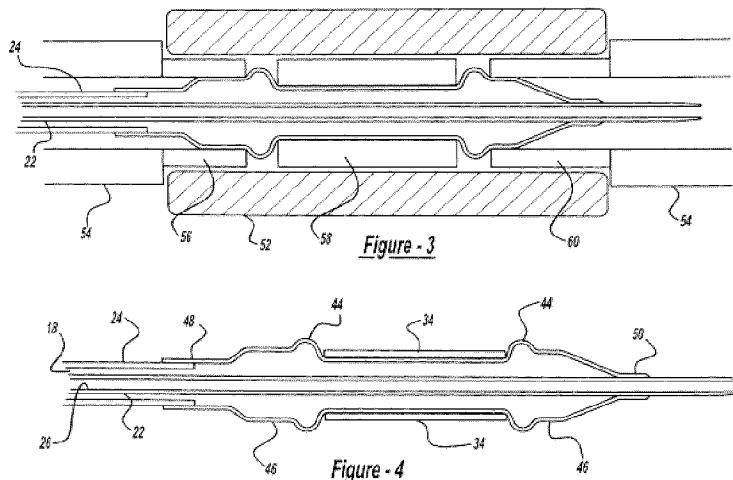
The Office Action rejected claims 1-4 and 9 under 35 U.S.C. § 102(b) as being anticipated by or in the alternative, under 35 U.S.C. § 103(a) as obvious over European Publication No. EP 1132059 (*Johnson*). Applicants respectfully assert that because *Johnson* fails to teach, suggest, or provide an apparent reason for modification to achieve the elements of the rejected claims, a *prima facie* case of anticipation or obviousness has not been established.

Johnson teaches a method for shaping a balloon for use in a balloon catheter system for the expansion of stents within the vasculature of a patient. As shown in Figures 3 and 4, below,

¹ Although the prior art status of the cited art is not being challenged at this time, Applicants reserve the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

the balloon 12 is formed such that it has "a pair of round annular shoulders immediately adjacent the proximal and distal ends of the stent" (Paragraph 22). The shoulders are formed by slipping a stent around a balloon, crimping the stent around the balloon, placing the stent and balloon in a mold, and inflating the balloon to a pressure slightly exceeding the burst pressure of the balloon (Paragraphs 33-34). As shown in Figure 3, the mold includes proximal, central, and distal tubes, 56, 68, and 60 positioned such that the proximal and distal balloon shoulders are allowed to expand (Paragraph 35). As noted by the Examiner, in some embodiments, the stent may be omitted during the shoulder-forming process and a "plastic phantom stent" may be used (Paragraph 41). The plastic phantom stent may "be provided with a longitudinal slit or preferably a spiral cut" to facilitate removal (Paragraph 41).



In contrast, claim 1 recites a method including the steps of "creating protrusions on the balloon by wrapping a member around the balloon such that spaced-apart loops of the member wrapped around the balloon compress the balloon leaving uncompressed portions of the balloon between the spaced apart loops of the member wrapped around the balloon to form the protrusions on the balloon; leaving the member wrapped around the balloon for a predetermined period of time; removing the member from the balloon after the predetermined period of time; and positioning a stent defining a plurality of apertures around the balloon such that the protrusions extend through the plurality of apertures defined by the stent.

The only protrusions disclosed by Johnson are the shoulders (44) located adjacent the proximal and distal ends of the stent. The shoulders (44) are not located "between the spaced apart loops of the member wrapped around the balloon" if the "member" is considered to be the stent or plastic phantom stent.

There is further no teaching suggestion or apparent reason in *Johnson* for the formation of protrusions that are capable of "extend[ing] through the plurality of apertures defined by the stent," as recited in claim 1. As noted above, the stent in *Johnson* is surrounded by a tube (58) during formation of the shoulders (44) (See Paragraph 36; Figure 7, elements 34, 58). Accordingly, protrusion of any portion of the balloon through the stent (34) is inhibited by the tube 58, particularly where the stent (34) is pressed tightly against the tube due to pressure exceeding the burst pressure of the balloon applied during the formation step. Furthermore, the balloon can only recede from the tube (58) and stent (34) upon relaxation of the balloon following relief of the pressure rather than extend therethrough.

II. REJECTION UNDER 35 U.S.C. 103

The Office Action rejected claims 5-8 and 11-15 under 35 U.S.C. § 103(a) as being unpatentable over *Johnson* in view of U.S. Patent No. 5,308,356 (*Blackshear*). Claims 10, 17, and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Johnson*.

Blackshear has been cited as showing a balloon formed in a mold. Col. 6, lines 41-46. Applicants respectfully assert that notwithstanding this teaching *Blackshear* fails to remedy the deficiencies of *Johnson* noted above with respect to claim 1 upon which claims 5-8 and 11-15 depend. A *prima facie* case of obviousness has therefore not been established with respect to claims 5-8 and 11-15.

With respect to claims 10, 17, and 18, the Office Action alleges without citation of a prior-art reference that it is well known in the art to fold balloons, either by hand or using a machine. Applicants respectfully object to the taking of Official Notice and request that references be cited supporting the allegation. Applicants further respectfully assert that this allegation fails to remedy the deficiencies of *Johnson* noted above with respect to claim 1, upon which claims 10, 17, and 18 depend. A *prima facie* case of obviousness has therefore not been established with respect to claims 10, 17, and 18.

C. PATENTABILITY OF ADDED CLAIMS

By this amendment claims 21-27 are added. Although not identical in scope claims 21-27 are believed to be allowable for at least some of the reasons noted above with respect to claim 1.

D. CONCLUSION

In view of the foregoing, Applicants respectfully submit that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicants acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicants reserve the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicants specifically request that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicants respectfully submit that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 10th day of August, 2009.

Respectfully submitted,

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